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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/620,462	07/17/2003	Catherine Rougeot	240156US0DIV	9166

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ALEXANDRIA, VA 22314

EXAMINER

CANELLA, KAREN A

ART UNIT	PAPER NUMBER
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1643

DATE MAILED: 06/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/620,462

Applicant(s)

ROUGEOT ET AL.

Examiner

Karen A. Canella

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☐ Claim(s) 51-77 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 51-77 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) *NOTED SET LCA*
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 10/17/2003 7/17/03
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_

### DETAILED ACTION

Claims 1-50 have been canceled. Claims 51-77 have been added and are examined on the merits.

#### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 51-77 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

(A) As drawn to method claims reliant on the identity of the target receptor of a XQHNPR peptide.

The instant method claims are reliant on the identity of a target receptor which is bound by the XQHNPR peptide in order to discern agonists and antagonists of said peptide. The specification provides no structural characterization of said receptor and provides only two properties attributed to said receptor, that of a pI value and the binding of the XQHNPR peptide. The specification states that there are at least two population of said receptors because two substances which bind to the XQHNPR peptide can be isolated having different pI values (page 77, lines 11-18).

*Taken together, these results suggest that at least 2 molecular populations of receptor sites for the SMR1-pentapeptide are present: one with a pHi of 5.58/5.64. +-.0.30, mainly represented in the medulla of kidney, pancreas and in a lesser extend in bone trabecular- and dental dentinal-matrix, and the other with a pHi of 6.62. +-.0.35, mainly represented in the glandular gastric mucosa. The third population with a pHi of 4.5. +-.0.4 that is present in the bone trabecular*

*matrix needs further confirmation, for the presence of high amounts of mineral components in that matrix may introduce some modifications in the parameters of IEF separation*

and that the molecular weight may range between 100kDa and 200kDa(page 76, lines 9-14).

This fails to provide support for any structural attribute of the putative receptor because it is not possible to ascertain a protein structure by a molecular weight range and pI value. Thus the targets receptor to which the agonists and antagonists must bind remains un-described. It logically follows that the method reliant of the identity of the target receptor is not adequately described.

(B) As drawn to biologically active derivatives obtained by the methods of claims 51, 59 and 65.

Claims 75-77 are drawn to biologically active derivatives obtained by the method of claims 51, 59 and 65, respectively. Even in the event that said method claims had adequate written description in the specification, the products obtained by using said methods could not be adequately described because it is not possible to describe a product yet to be identified.

Claims 75-77 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is undue include, but are not limited to: 1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level of predictability in the art, 5) existence of working examples, 6) breadth of claims, 7) amount of direction or guidance by the inventor, and 8) quantity of experimentation needed to make or use the invention. In re Wands, 858 F.2d 731, 737.8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

The instant claims are drawn to biologically active derivatives obtained by the methods of claims 51, 59 and 65. The requirements of 112, first paragraph are that one of skill in the art can make and use the instant invention without undue experimentation. In the instant case, it would be necessary to first carry out the method of claims 51, 59 and 65 to identify compounds

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which are agonists and antagonists of the XQHNPR peptide in order to find the appropriate molecules which are not excluded by the limitations of claims 75-77. Thus, it would be undue experimentation in the making and using of the instant claimed derivatives because one of skill in the art would first be forced into carrying out the methods of claims 51, 59 and 65 in order to identify a molecule which would fulfill the limitations of claims 75-77 before being able to make and use said molecule.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

An obviousness-type double-patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is either anticipated by, or would

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have been obvious over, the reference claim(s). See, e.g. In re Berg, 140 F.3d, 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

Claims 75-77 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 18-28 of copending Application No. 10/315,445. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '445 application anticipate the instant claims because the peptidomimetic fulfills the limitations of the instant "biologically active derivative"..

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 75-77 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 17, 20-22 and 31 of copending Application No. 10/435,564. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '564 application anticipate the instant claims as they encompass the biologically active derivatives of the instant claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 65-68, 70 and 71 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 15 of copending Application No. 10/451,073. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claim of the '073 application anticipates the instant claim because measurement of NEP substrate hydrolysis fulfills the specific embodiment of the instant claim 65 requiring the measurement of a metabolic change, and the terms cell culture, organ specimen and tissue sample encompass the limitations of the instant dependent claims 66-68, 70 and 71.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Canella whose telephone number is (571)272-0828. The examiner can normally be reached on 10-6:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571)272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Karen A. Canella, Ph.D.

6/24/2006

  
KAREN A. CANELLA PH.D.  
PRIMARY EXAMINER